IEEE

PSES

Product Safety Engineering Society

San Diego Chapter

Patient and Operator – different requirements IEC 60601-1:2005 Ed. 3 + Amd. 1:2012 (ie, Ed. 3.1)

Grant Schmidbauer, Nemko USA, Inc.

10 December 2013

Abstract

- IEC 60601-1, Ed. 3 was published in 2005, and Amendment 1 in 2012 (now called Ed. 3.1)
- With it's introduction, there are significantly different requirements for the patient compared for the operator
- The standard has introduced Means of Patient Protection (MOPP) for the patient
- The standard has introduced Means of Operator Protection (MOOP) for the operator

Abstract

- The basis of the introduction of MOPP and MOOP is that for many types of Medical equipment, the operator is a healthy (normal) person, and the Medical equipment has an interface much like a computer, therefore why treat the operator as a patient
- As a result, there is now a distinction of treating (protecting) the operator and the patient differently

Abstract

- MOPP is based on the similar protection afforded by IEC 60601-1 Ed. 2 ; whereas MOOP is based on the protection afforded by IEC 60950-1

- This presentation will look into the main differences between MOPP and MOOP

Definitions

- 3.58 Means of Operator Protection (MOOP)
  Means of protection (MOP) for reducing the risk due to electric shock to persons other than the patient
- 3.59 Means of Patient Protection (MOPP)
  Means of protection (MOP) for reducing the risk due to electric shock to the patient
- 3.76 Patient
  living being (person or animal) undergoing a medical, surgical or dental procedure
  (Note: A patient can be an operator)

Applied part

- 3.8 Applied part
  Part of ME equipment that in normal use necessarily comes into physical contact with the patient for ME equipment to perform its function
- 5.9.1 Applied parts
  Applied parts are identified by inspection and by reference to the accompanying documents
- 7.9.2.5 ME Equipment description
  The instructions for use shall indicate any applied part

Applied parts

- 4.6 ME Equipment or ME System parts that contact the patient:
  RMF shall include an assessment of whether parts that can come into contact with the patient but fall outside of the definition of applied parts need to be subject to the requirements for applied parts.
  The requirements for a Type B applied part shall apply unless the risk management process identifies a need for Type BF or Type CF (except for marking)

MOPP versus MOOP

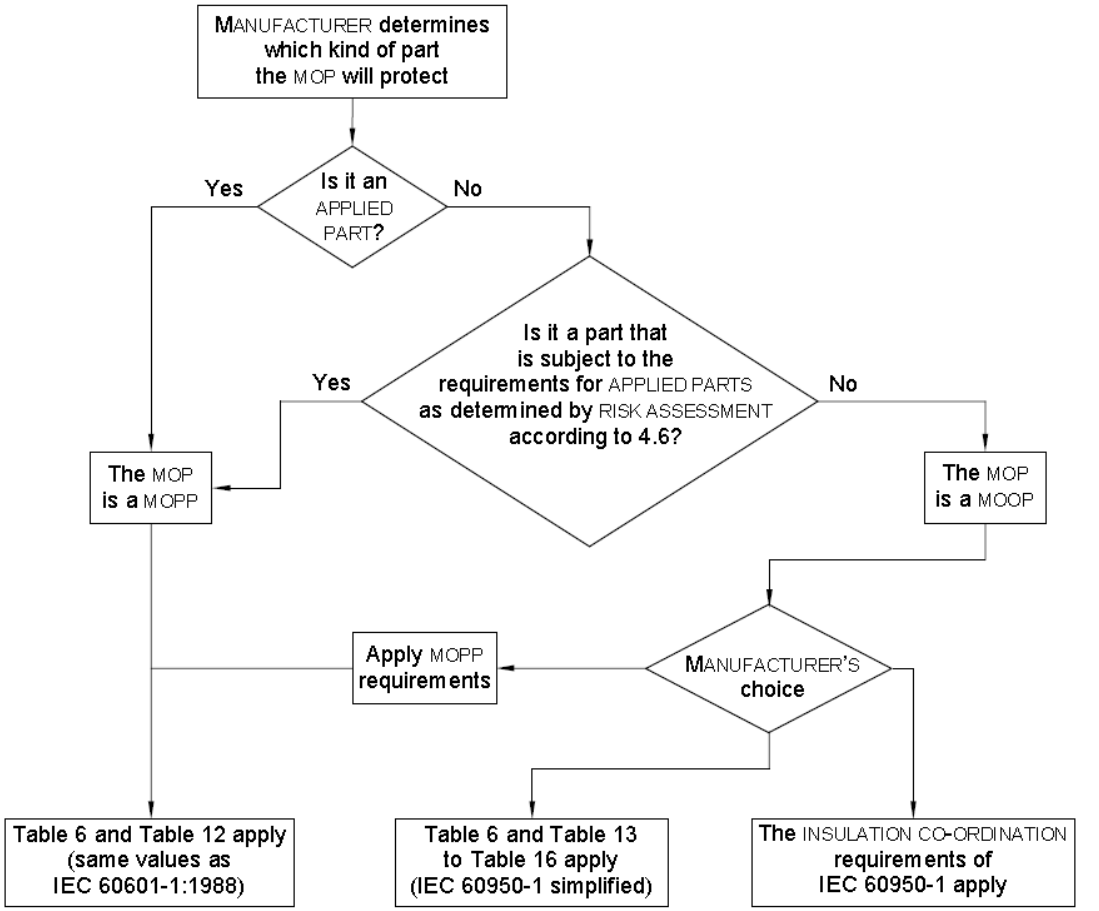

Figure A.12 – Identification of MEANS OF PATIENT PROTECTION and MEANS OF OPERATOR PROTECTION

Product Safety Engineering Society

Protection against electrical hazards

- 8.5.1 Means of protection (MOP):

  ME Equipment shall have two means of protection (MOP) to prevent applied parts and other accessible parts from exceeding the limits
  - One means of protection (1MOP) = BI/SI
  - Two means of protection (2MOP) = DI/RI

  Each means of protection shall be categorized as MOPP or MOOP

Protection against electrical hazards

- 8.5.1.2 Means of patient protection (MOPP):

  - Creepage distances (CR), air clearance (CL) and dielectric strength are based on same requirements as IEC 60601-1 Ed. 2

  - Protective earth connections forming a means of patient protection shall comply with the requirements for protective earthing

  - A Y capacitor (Y1 or Y2 only) complying with IEC 60384-14 is considered equivalent to one MOPP

Protection against electrical hazards

- 8.5.1.2 Means of patient protection (MOPP):

  - Where two Y capacitors are used in series, they shall be identical in type (either both Y1 or both Y2) and shall have the same nominal capacitance.

  - The capacitor(s) shall meet the dielectric strength for the type of protection for which they are being used (i.e. one or two MOPP)

  - Where the working voltage across a barrier forming a MOPP is less than 42.4Vpk/ac or 60Vdc, a single Y1 capacitor is acceptable for two MOPP

Protection against electrical hazards

- Rationale 8.5.1 Means of protection (MOP):
  - Y1 capacitor:
    - working voltage: 500Vac
    - withstand voltage: 4000Vac
  - Y2 capacitor:
    - working voltage: 300Vac
    - withstand voltage: 1500Vac
  - Y3 capacitor:
    - working voltage: 250Vac
    - withstand voltage: 1500Vac
  - Y4 capacitor:
    - working voltage: 150Vac
    - withstand voltage: 1000Vac

Protection against electrical hazards

- Rationale 8.5.1.2 Means of patient protection (MOPP):

  - When fitting Y capacitors across barriers, the dielectric strength requirement must be considered

  - For eg., for voltages in the range of 212Vpk to 354Vpk (ie, 250Vac), two MOPP are required to be tested at 4000Vac

  - This would then require the use of Y1 capacitors

Protection against electrical hazards

- Rationale 8.5.1.2 Means of patient protection (MOPP):

  - Two Y2 capacitors in series would not withstand this voltage as they are rated at 1500Vac each

  - For voltages below 212 V peak (ie, 150Vac), two Y2 capacitors would suffice as the dielectric strength requirement is 3000Vac

Protection against electrical hazards

- 8.5.1.3 Means of operator protection (MOOP):

  - Creepage distances (CR), air clearance (CL) and dielectric strength are based on similar requirements as IEC 60950-1

  - Protective earth connections forming a means of patient protection shall comply with the requirements for protective earthing

  - A Y capacitor (Y1 or Y2 only) complying with IEC 60384-14 is considered equivalent to one MOOP

Protection against electrical hazards

- 8.5.1.3 Means of operator protection (MOOP):

  - Where two capacitors are used in series, they shall be identical in type (either both Y1 or both Y2) and shall have the same nominal capacitance.

  - The capacitor(s) shall meet the dielectric strength for the type of protection for which they are being used (i.e. one or two MOOP)

  - A Y1 capacitor can be used for two MOOP

Protection against electrical hazards

- 8.8.3 Dielectric strength
  Considering 250Vac mains part

  - MOPP based on IEC 60601-1 Ed. 2
    Table 6: 1MOPP: 1.5kV; 2MOPP: 4.0kV
  - MOOP based on IEC 60950-1
    Table 6: 1MOOP: 1.5kV; 2MOOP: 3.0kV

  Note: Previous concept of A-xx (accessible part) replaced by MOOP and B-xx (applied part) replaced by MOPP

Protection against electrical hazards

- 8.9 Creepage distances (CR) and air clearances (CL):
  Considering 250Vac mains part
  - MOPP based on IEC 60601-1 Ed. 2
    Table 12 CL: 1MOPP: 2.5mm; 2MOPP: 5mm
    Table 12 CR: 1MOPP: 4mm; 2MOPP: 8mm
  - MOOP based on IEC 60950-1
    Table 13 CL: 1MOOP: 2mm; 2MOOP: 4mm
    Table 16 CR: 1MOOP: 2.5mm; 2MOOP: 5mm

  Note: Previous concept of A-xx (accessible part) replaced by MOOP and B-xx (applied part) replaced by MOPP

Insulation diagram

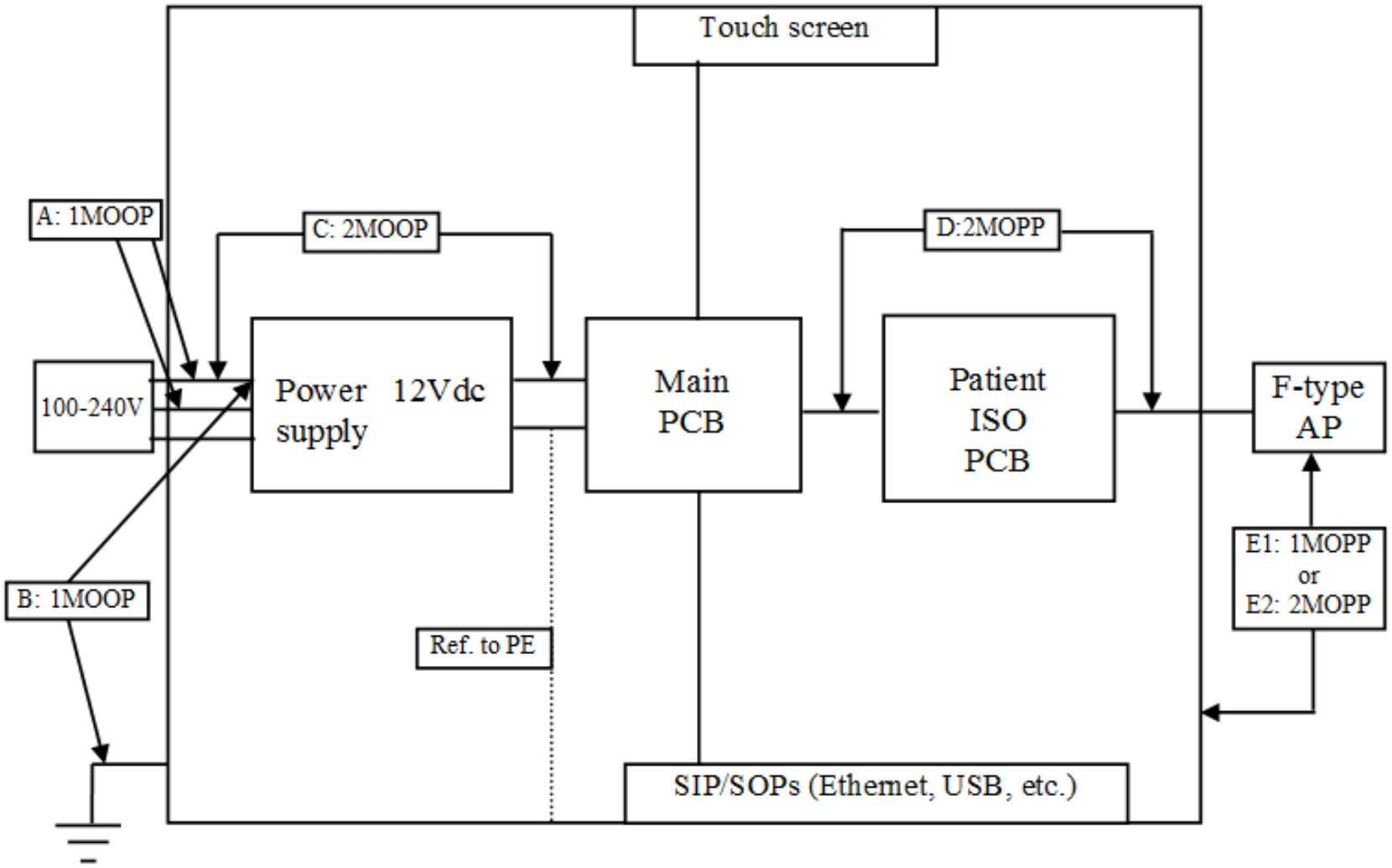

Table to insulation diagram

TABLE: To insulation diagram		
Pollution degree .....:	2	—
Overvoltage category.....:	II	—
Altitude .....:	<2000m	—
Additional details on parts considered as applied parts .....:	☒ None ☐ Areas _____ (See Clause 4.6 for details)	—

Area	Number and type of Means of Protection: MOOP, MOPP	CTI (IIIb, unless is known)	Working voltage Vrms	Working voltage Vpk	Required creepage (mm)	Required clearance (mm)	Measured creepage (mm)	Measured clearance (mm)	Remarks
A	1MOOP	IIIb	240	339	2.5 (*)	2.0 (*)			[1] Line to line
B	1MOOP	IIIb	240	339	2.5	2.0			Mains to PE
C	2MOOP	IIIb	240	339	5.0	4.0			Mains to sec
D	2MOPP	IIIb	12Vdc	12Vdc	3.4	1.6			Sec to AP
E1	1MOPP	IIIb	240	339	4.0	2.5			[2] AP to PE
E2	2MOPP	IIIb	12Vdc	12Vdc	3.4	1.6			[2] AP to PE

Supplementary information:

[1] Area A: 1MOOP (mains of opposite polarity): Change from Ed. 3.0: CR/CL: 3.0/1.6mm; to Ed. 3.1: CR/CL: 2.5/2.0mm
Alternative, according to IEC 60950-1, maybe treated as:
Basic insulation: Creepage: 2.5mm; Air clearance: 2.0mm (same as IEC 60601-1 Ed. 3.1)
Functional insulation: Creepage: 2.5mm; Air clearance: 1.5mm
Functional insulation: Withstand electric strength test for Functional insulation in 5.2.2 (1500Vac)
[2] Area E: Two options according to "special rules" in rational to subclause 8.9:
E1: Basic insulation according to 250Vac mains working voltage; or
E2: Double/reinforced insulation according to (12Vdc secondary) working voltage; whichever is worst case

Table to dielectric strength

8.8.3	TABLE: Dielectric strength test of solid insulating materials with safety function – means of operator protection (MOOP) / means of patient protection (MOPP)	

Insulation under test (area from insulation diagram)	Insulation Type (1 or 2 MOOP/MOPP)	Reference Voltage		A.C. test voltages in V r.m.s[1]	Dielectric breakdown after 1 minute Yes/No[2]
		Peak working voltage (U) V peak	Peak working voltage (U) V d.c.		
A: Line to line	1MOOP	339	—	1500	
B: Mains to PE	1MOOP	339	—	1500	
C: Mains to sec	2MOOP	339	—	3000	
D: Sec to AP	2MOPP	—	12Vdc	1000	
E1: AP to PE	1MOPP	339	—	1500	
E2: AP to PE	2MOPP	—	12Vdc	1000	

Supplementary information:

[1] Alternatively, a d.c. test voltage equal to the peak value of the a.c. test voltage used.

[2] A) Immediately after humidity treatment of 5.7, ME equipment de-energized, B) after required sterilization procedure, ME equipment de-energized, C) after reaching steady state operating temperature as during heating test of 11.1.1, and D) after relevant tests of 11.6 (i.e., overflow, spillage, leakage, ingress of water, cleaning, disinfection, and sterilization).

Contact information

Grant Schmidbauer
Nemko USA, Inc.
2210 Faraday Ave., Suite 150
Carlsbad (San Diego), CA 92008 USA
Tel: 760-444-3413
Fax: 760-444-3005
Email: grant.schmidbauer@nemko.com
Website: www.nemko.com